REMARKS

The Action states that claims 22-33, 36-65 and 74-87 are pending and stand rejected as final. Applicants disagree with the status of the claims. In particular, there is no indication of the status of claims 1-3, 5, 6, 8-10, 21, 34, 35 and 66-73, suggesting that they have been canceled. Instead, these claims should have been indicated as merely withdrawn from consideration, as per the preceding Office Action. However, this is now a moot point with respect to claims 1-3, 5, 6, 8-10, 21, 34 and 35, as Applicants have canceled these claims without prejudice or disclaimer to the subject matter claimed therein. Claims 22, 31, 39, 42 and 66 have been amended. New claims 88-92 have been added.

Applicants respectfully submit that these after-final amendments are proper because the amendments are submitted in connection with a Request for Continued Examination.

Applicants believe that a brief review of the invention would be helpful to its understanding.

The present invention pertains to a prosthetic device containing fibers that are at least partially aligned. In particular, the fibers are arranged as a plurality of plates of aligned fibers; however, the plates may or may not be aligned with respect to one another. Prosthetic devices can be used in the repair, augmentation or replacement of diseased or damaged organs such as muscles (e.g., rotator cuff injuries), intervertebral disc, ligaments, or defects in the *dura mater* or abdominal wall, among other applications. The fibrous prosthetic devices of the present invention are structurally stable, pliable, suturable, and can be made porous or non-porous.

Such a fibrous prosthetic device may be prepared by providing a slurry or fibrous dough containing at least a plurality of biodegradable polymer fibers in a fluid, optionally also containing a lubricant. In a simple embodiment, the slurry or fibrous dough may be placed between two platens and uniaxially compressed. The fibers begin to align in directions that are radial to the compression axis.

Claim Rejections – 35 USC §102

Claims 22-33, 38-45, 47-49, 51-53, 61-65, 74-77, 80-81, 84 and 87 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,158,574 to Stone (hereinafter referred to as "Stone"). Claims 22-30, 37-48, 51-65, 74-84 and 87 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Application Publication No. US2002/0127270 to Li (hereinafter referred to as "Li"). Applicants respectfully traverse these rejections.

Each of these rejections comes down to the position of the Office that the claimed implant and that of Stone and Li are produced in the same manner and contain the same components, and that therefore all of the physical limitations are met. The Action cites In re Best for the rule that

> "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. Thus, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable."

Applicants respectfully submit that neither Stone nor Li discloses or suggests the claimed invention.

Stone discloses a biocompatible and bioresorbable structure for implantation into the knee joint which assumes the form and role of a meniscus. This prosthetic meniscus promotes and provides a scaffold for the regeneration of tissue. In some forms of the Stone invention, the fibers may be randomly oriented throughout the matrix. Alternatively, the fibers may be substantially circumferentially extending or substantially radially extending throughout the prosthetic meniscus. The matrix may also include glycosaminoglycans (GAGs) interspersed with the fibers.

The Stone method for fabricating a prosthetic meniscus includes placing a plurality of fibers and/or fibers and GAGs into a mold having a shape useful for knee joint function, subjecting the fibers (and GAGs) in the mold to two cycles of freezing and thawing, contacting the fibers or fibers and GAGs with a chemical crosslinking agent such that the fibers then assume the shape of the mold, and lyophilizing the resulting structure to obtain a dry, porous, volume matrix. In at least one embodiment, the mold contents are uniaxially compressed (see Example 1).

Li discloses a sheet membrane containing at least one layer of oriented biopolymeric fibers, such as collagen fibers. The Li method includes reconstituting biopolymeric fibers dispersed in a solution, placing the reconstituted biopolymeric fibers around a mandrel, rotating the mandrel to convert the reconstituted biopolymeric fibers on the mandrel into a tubular membrane of oriented biopolymeric fibers, cutting the tubular membrane longitudinally after it has been dried on the mandrel, rolling the cut membrane into a tubular form that is an inversion of the tubular membrane, inserting the rolled membrane into a tubular mesh, and crosslinking the biopolymeric fibers to form a sheet membrane or oriented biopolymeric fibers.

In contrast, the claimed method for producing an implantable device features fibers that migrate through a fluid that flows in directions outward or away from, for example, substantially lateral or orthogonal to the axis of compression. Applicants respectfully submit that the Stone and Li methods are different. In particular, Stone provides a mold having a component containing perforations. As compression takes place, the fluid flows through the perforations. The important point is that the fluid flows substantially parallel to the compression axis in Stone. In Li, there is no migration of fibers through a fluid as

compression occurs, as the fibers are aligned as they are wound on the rotating mandrel. The compression of Li simply squeezes excess fluid out of the wound, aligned fibers.

Thus, the methods of stone and Li are each different from those giving rise to the compressed fibrous implants of the present invention. Accordingly, the Action cannot conclude that the respective products would inherently be the same.

In fact, Applicants respectfully submit that neither Stone nor Li discloses or suggests the claimed implants comprising plates of aligned fibers.

Thus, the claimed invention is patentably distinguishable over the products of Stone and Li. Accordingly, Applicants respectfully request that these rejections be withdrawn.

Claim Rejections – 35 USC §103

Claims 22-33, 36-65 and 74-87 were rejected under 35 U.S.C. §103(a) as being unpatentable over Stone in view of Li and further in view of U.S. Patent No. 6,428,576 B1 to Haldimann. Applicants respectfully traverse this rejection.

The Action applied Haldimann primarily to show that the use of plasticizers and particulates in implantable bio-polymers was well known to the skilled artisan at the time of the invention. Applicants have shown that neither Stone nor Li discloses or suggests the claimed invention. Applicants respectfully submit that Haldimann fails to remedy the deficiencies in Stone and in Li. Specifically, Haldimann likewise fails to disclose or suggest the claimed implants featuring aligned fibers in the form of plates. Nor does Haldimann disclose or suggest the claimed method of making implant, featuring compressing a fibrous dough in one or more dimensions, and having the fluid of the fibrous dough be expelled in a direction away from the compressing direction(s).

Accordingly, this rejection should be withdrawn.

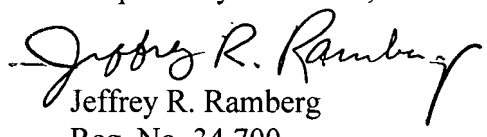
CONCLUSION

The processes of Stone and Li are each different from the claimed method, whereby fluid migrates to the side, or away from, the direction of compression of the fibrous dough. Further, neither Stone nor Li discloses or suggests the claimed articles featuring a plurality of plates of aligned fibers.

In view of the amendments and the above remarks, Applicants respectfully submit that the instant application is in condition for allowance. Accordingly, Applicants respectfully request issuance of a Notice of Allowance directed to claims 22-26, 28-33, 36-50, 52-65 and 74-92.

Should the Examiner deem that any further action on the part of Applicants would be desirable, the Examiner is invited to telephone Applicants' undersigned representative.

Respectfully submitted,



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